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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/049,568 | 02/15/2002 | Klaus Duecker | MERCK 2379 | 7502 |

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| EXAMINER | |
|---|---|
| NICHOLS, CHRISTOPHER J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/049,568 | DUECKER, KLAUS | |
| | Examiner | Art Unit | |
| | Christopher Nichols, Ph.D. | 1647 | |

*-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Status of Application, Amendments, and/or Claims*

1. The Amendment/Response filed 3 September 2003 has been received and entered in full.

2. Claims 1, 4, 6, 7, 8, and 11 have been amended. Claims 12-14 have been added. Claim 10 is withdrawn from consideration.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Withdrawn Objections And/Or Rejections*

4. The Objection to the Specification as set forth at pp. 3 ¶4-5 is *withdrawn* in view of Applicant's amendments (3 September 2003).

5. The Objections to claims 1, 7, and 8 as set forth at pp. 3 ¶6 is *withdrawn* in view of Applicant's amendments (3 September 2003).

6. The Rejection of claims 1, 4, 6, 7, 8, 9, and 11 under 35 U.S.C. §112 ¶2 as set forth at pp. 17-18 ¶13 is *withdrawn* in view of Applicant's amendments (3 September 2003).

### *New/Maintained Rejections And/Or Rejections*

7. Claim **14** is objected to because of the following informalities: "whrein" is misspelled. Appropriate correction is required.

8. Claims **1-9 and 11-14** are rejected under 35 U.S.C. §101 because the claimed invention is not supported by a specific, substantial, and credible asserted utility or a well-established utility for the reasons set forth at pp. 3-14 ¶7-10 in the previous Office Action (6 March 2003).

9. Applicant traverses this rejection in the Response filed 3 September 2003 for the following reasons: (a) the claimed GPCR (G-protein coupled-receptor) HGRL101 is a new form of the relaxin receptor, (b) HGRL101 shares 94% sequence identity and 95% sequence similarity with LGR7, a known relaxin receptor (Exhibit 1 and 2) and this is sufficient to establish utility (Exhibit 10).

10. Applicant's arguments and Exhibits have been taken into full consideration and are not found persuasive for the following reasons.

11. Concerning (a), as set forth at pp. 14 ¶10 of the previous Office Action (6 March 2003):

> If Applicant can submit evidence (in the form of a declaration under 37 CFR 1.132 or post-filing date publications) supporting the specification's assertion that SEQ ID NO: 2 has a specific function similar to a known G-protein coupled receptor (GPCR), wherein the specific function was predicted by the specification as originally filed, such would be viewed favorably as evidence of patentable utility.

12. The Specification as filed does not contain any support for the identity of SEQ ID NO: 2 as a relaxin receptor. Therefore the identity of SEQ ID NO: 2 was not correctly predicted by the specification as originally filed.

13. Concerning (b), and the USPTO *Utility's Guideline Training Materials*, in Example 10 therein the Applicant asserted that the novel isolated DNA encoded a ligase and shared 95% similarity to known ligase and thus was held to have utility. This is not the same fact pattern as

the instant case. The instant Specification does not correctly assert or identify the novel polypeptide (SEQ ID NO: 2) as a relaxin receptor.

14. Thus the rejection of claims 1-9 and 11-14 under 35 U.S.C. §101 is maintained.

15. Claims **1-9 and 11-14** are also rejected under 35 U.S.C. §112 ¶1. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for the reasons set forth at pp. 15-16 ¶11 in the previous Office Action (6 March 2003).

16. Applicant traverses this rejection in the Response filed 3 September 2003 for the following reasons: (a) the claimed GPCR (G-protein coupled-receptor) HGRL101 is a new form of the relaxin receptor, therefore has a known utility and thus the rejection under 35 U.S.C. 112 ¶1 is *moot.*

17. Applicant's arguments and Exhibits have been taken into full consideration and are not found persuasive for the following reasons. As discussed above, the Specification as originally filed does not contain support for the identity of SEQ ID NO: 2 as a relaxin receptor and therefore does not have support for its utility as a relaxin receptor.

18. The rejection of claims 1-9 and 11-14 under 35 U.S.C. §112 ¶1 is hereby maintained.

19. Claims **1, 4, 5, 6, 7, 8, 9, 11, 12, 13, and 14** are rejected under 35 U.S.C. §112 ¶1, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention for the reasons set forth at pp. 16-17 ¶12 in the previous Office Action (6 March 2003).

20. Applicant traverses this rejection in the Response filed 3 September 2003 for the following reason: (a) "fragments and variants" are clearly defined in the specification; (b) the claims contain the limitation of "immunospecific" for HGR101.

21. Applicant's arguments and Exhibits have been taken into full consideration and are not found persuasive for the following reasons. As discussed above, the Specification as originally filed does not contain support for the identity of SEQ ID NO: 2 as a relaxin receptor and therefore does not have support for its utility as a relaxin receptor. Further, the definition of "fragments" does not contain any functional language or further limitations. To the contrary, the newly added claims defining the fragments of SEQ ID NO: 2 as single amino acids with the exception of amino acid positions 93-97 which spans 4 amino acids.

22. Next, the Specification as filed does not support single amino acids or tetrapeptides as having "HGR101" immunospecificity or biological activity.

23. Furthermore, the amendment of claim 11 and the addition of claim 12 as a new claim adds additional grounds for rejection under the written description portion of §112 ¶1 in that the compounds to be manufacture have not been isolated, described, or disclosed in any manner that would allow a skilled artisan to be apprised of their structure.

24. The rejection of claims 1, 4, 5, 6, 7, 8, 9, 11, 12, 13, and 14 under 35 U.S.C. §112 ¶1 is hereby maintained.

25. Claims **1, 4, 6, 7, 8, 9, 11, 13, and 14** are rejected under 35 U.S.C. §102(b) as being anticipated by US 5756309 (26 May 1998) for the reasons set forth at pp. 18-19 ¶14-15 in the previous Office Action (6 March 2003).

26. Applicant traverses this rejection in the Response filed 3 September 2003 for the following reason: (a) "fragments and variants" are clearly defined in the specification in such a way that US 5756309 does not anticipate the claims.

27. Applicant's arguments and Exhibits have been taken into full consideration and are not found persuasive for the following reasons. As discussed above, the Specification as originally filed does not contain support for the identity of SEQ ID NO: 2 as a relaxin receptor and therefore does not have support for its utility as a relaxin receptor. Further, the definition of "fragments and variants" does not contain any functional language or further limitations as to exclude the polypeptides and polynucleotides of US 5756309. To the contrary, the newly added claims defining the fragments of SEQ ID NO: 2 as single amino acids with the exception of amino acid positions 93-97 which spans 4 amino acids are clearly anticipated under 35 U.S.C. 102(b) by US 5756309.

28. The rejection of claims 1, 4, 6, 7, 8, 9, 11, 13, and 14 under 35 U.S.C. §102(b) is hereby maintained.

***Summary***

29. Claims **1-9 and 11-14** are hereby rejected.

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elyabeth C. Kemmerer

CJN
October 7, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER